In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 16-1478V
(to be published)

* *

PHILIP NGO, *as father and legal guardian of* A.N., *a minor,*

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Special Master Corcoran

Filed: September 18, 2017

Decision Without Hearing; Dismissal; Measles-Mumps Rubella ("MMR") Vaccine; Autism Spectrum Disorder ("ASD").

Philip Ngo, pro se, Portland, OR, for Petitioner.

Linda Renzi, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CASE[1]

On November 9, 2016, Philip Ngo, on behalf of his daughter, A.N., filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] In it, Petitioner alleged that the measles-mumps-rubella ("MMR") vaccine A.N. received on November 18, 2013, caused her to develop an autism spectrum disorder ("ASD"). Petition at 1.

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[1] This Decision will be posted on the Court of Federal Claims's website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the decision will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the Decision in its present form will be available. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

After some of the medical records were filed, Respondent filed his Rule 4(c) Report. *See* Respondent's Rule 4(c) Report, filed on June 7, 2017 (ECF No. 18) ("Rule 4"). Shortly thereafter, I issued an order directing Petitioner to show cause why his case should not be dismissed based on its factual similarity to other unsuccessful autism claims. *See* Order to Show Cause, dated June 28, 2017 (ECF No. 20) ("OSC"). Petitioner filed a letter on August 10, 2017 attempting to support his claim. *See* Letter, filed Aug. 10, 2017 (ECF No. 22). Respondent has not filed a brief in reaction.

I. FACTUAL BACKGROUND

There have been less than one hundred pages of medical records filed in this case, despite my allowing Petitioner nearly six months to perform record collection.[3] The records filed include A.N.'s vaccination record, lab results from a few months post-vaccination, and records for treatment and evaluations A.N. received a year or more after vaccination.

A.N. was born on November 7, 2012, but no birth or pregnancy records were ever filed, making it difficult to determine if A.N. (or her mother) had any health complications. Petitioner's Medical Records 1 at 5 ("MR1"). Later doctor's visits elicited statements from Petitioner indicating that although A.N.'s mother was 40 years old, it was an uncomplicated pregnancy and delivery. MR1 at 2. In her first few months of life, A.N. was described as healthy without any major illnesses, and she began crawling at four months and babbling at 3 months of age. *Id.*

Presumably at her one year well-child exam, on November 18, 2013, A.N. received her hepatitis A and MMR vaccines. MR1 at 29, 33. There has been no record evidence or reports submitted that A.N. had an immediate reaction after her vaccines. Rather, it appears that Petitioner first became concerned about A.N. between 16-18 months of age (four to six months after vaccination), when he reported her babbling had reduced. *Id.* at 29.

A.N. was first evaluated for autism on April 17, 2015, at Oregon Health and Science University ("OHSU"), when she was two years and five months old. It appears, however, that prior to this evaluation, A.N. was seen at Sellwood Family Medicine several times during 2014—beginning in May 2014, six months after vaccination. Petitioner's Medical Records 2 at 54-57 ("MR2"). There is no information about what was discussed at this visit, but a patient plan

[3] The original statement of completion deadline in this case was February 8, 2017. Initial Order, dated Nov. 11, 2016 (ECF No. 4). On February 2, 2017, Petitioner filed 59 pages of medical records, however, followed shortly by a status report filed by Respondent identifying outstanding records that needed to be filed. *See* Status Report, filed on Feb. 8, 2017. Petitioner later filed additional documents, but those documents were invoices for treatment rather than treatment records. *See* Medical Records, dated April 13, 2017.

was filed, which seems to indicate that A.N. was prescribed a new vitamin supplement regimen, and Petitioner was instructed on dietary modification to attempt to treat A.N.'s condition.[4] *Id.*

The notes from A.N.'s first evaluation for Autism at OHSU reveal that she was referred there by her primary health provider, John Njenga, PA, based on his concerns that A.N. was exhibiting autism symptoms. MR1 at 5. Dr. Lark Huang-Storms, PhD, was the psychologist that evaluated A.N. *Id.* at 4. In recording A.N.'s medical history, Dr. Huang-Storms noted that A.N. had not experienced any significant health issues as a child, except at 18 months old, when her father reported that she fell and hit her head on the floor. *Id.* at 5. Regarding A.N.'s developmental progression, Dr. Huang-Storms recorded the concerns of Petitioner about A.N. stopping babbling, her late ability to walk and toe-walking when she did begin walking, and that A.N. could not use words or make spontaneous gestures. *Id.* at 5-6. The conclusions of this visit were that A.N. was showing "significant symptoms of an Autism Spectrum Disorder (ASD)…repetitive behaviors (e.g. toe-walking, hand twisting/clapping), restricted interests (e.g., particular toys), limited joint attention, and does not use words or babble (most of her sound are made with a closed mouth)." *Id.* at 10.

A.N. has subsequently been evaluated by other providers who have similarly noted that A.N. shows significant symptoms of autism, and requires educational and therapeutic treatments. MR1 at 2-10, 23.

II. PARTIES' RESPECTIVE ARGUMENTS

Petitioner alleges that A.N. suffers from autism as a result of her receipt of the MMR vaccine in November 2013. Petition at 1. As stated previously, due to the large number of unsuccessful autism cases over the past ten year in the Vaccine Program, I ordered Petitioner to offer further support for his claim, or risk its dismissal. OSC at 1-2. Specifically, I instructed Petitioner to focus on distinguishing the facts of his case from those previously-dismissed autism cases. *Id.* at 2.

Petitioner attempted to do so in a letter, arguing a theory that the Centers for Disease Control ("CDC") had evidence (suppressed by the U.S. Government) that showed that the MMR vaccine has been linked to children developing autism. *See* Letter at 1. The short, two-page letter did not, however, address A.N.'s specific reaction, nor it did it contrast her condition from the other factual scenarios previously rejected by the Program.

Respondent chose not to file a brief reacting to the letter. In his Rule 4 (c) Report however, he stated that the case should be dismissed because no evidence of causation had been produced by Petitioner linking the MMR vaccine to A.N.'s condition. Rule 4 (c) Report at 5.

[4] Based on invoices, it appears that A.N. also began applied behavior analysis therapy after these visits. MR2 at 12.

In addition to the letter filed by Petitioner, the only causal evidence that has been presented was a two page statement written by Petitioner citing to studies which purport to link autism to vaccines. MR1 at 1-2.

IV. APPLICABLE LEGAL STANDARDS

A. Claimant's Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[5] Here, Petitioner alleges only a non-table injury.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1)

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[5] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Law Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous

medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneously medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute

and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. Determination to Resolve Case Without Hearing

I have opted to decide entitlement in this case based on written submissions and evidentiary filings filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Petitioners Cannot Meet Their Evidentiary Burden Given the Facts of this Case

After careful review of the medical records, and Petitioner's filings I conclude that Petitioner will not be able to establish preponderant evidence in favor of his claim, and therefore the matter should not proceed, even if expert reports have not yet been obtained. My decision is rooted in both the facts of this case as well as applicable decisions in previously-litigated matters involving causation theories highly similar to the present, and which have been exhaustively litigated since resolution of the Omnibus Autism Proceedings ("OAP") test cases.[6]

Petitioner's non-table causation-in-fact claim is not supported by the record evidence, which fails to attribute A.N.'s autism to the MMR vaccine. Nor is there record proof establishing any post-vaccination reaction that arguably could result in a developmental problem. Unlike many autism claims, Petitioner does not argue that A.N. suffered an encephalopathic reaction following closely with vaccination, nor is there any evidence of such a reaction.

Instead, Petitioner conclusory relies on the purported existence of epidemiological evidence showing an association between the MMR vaccine and autism, thus proving his claim. But reliable evidence in support of such contentions is non-existent.

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[6] Several years ago, more than 5,400 cases were initially filed under short form petition in the OAP, where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the measles, mumps, rubella ("MMR") vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately a total of eleven lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit, unanimously rejected petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines

The special masters presiding over the test cases in the OAP, after extensive research and testimony, rejected theories of causation connecting the MMR vaccine to autism. *See e.g., Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010). I find no compelling reason to diverge from those cases, as Petitioner has not offered evidence showing why A.N.'s case is different from those decided in the OAP, nor has he suggested a novel theory not previously considered in the OAP.

Give the above, it is evident that Petitioners cannot meet their burden under the analysis set forth in *Althen* for proving a causation-in-fact claim:

Prong One: Petitioner cannot present a reliable medical or scientific theory explaining how the MMR vaccine could cause autism. Even if I were to allow Petitioners time to hire experts and develop a theory, it is highly unlikely to be distinguishable from those that have been repeatedly advanced but rejected in the Program.

Prong Two: Petitioner's obligation under the second *Althen* prong was to demonstrate a logical sequence of cause and effect connecting the particular facts of their case to their medical theory. *See, e.g., Sturdivant v. Sec'y of Health & Human Servs.*, No. 07-788V, 2016 WL 552529, at *18 (Fed. Cl. Spec. Mstr. Jan. 21, 2016) (prong two requires a fact-based inquiry into whether the vaccine in question *did* cause the particular injury). But the medical record is bereft of reliable evidence that A.N. had any reaction to her vaccines nor did any treaters suggest it to be the case.

Prong Three: Even if I had accepted Petitioner's theory, A.N.'s developmental symptoms have not been shown to have occurred within a medically appropriate timeframe from the date of the November 2013 vaccinations. The lack of medical records filed in this case make this analysis more difficult, but even so it appears that evaluations for a developmental disorder did not occur until about six months after vaccination. Although some statements by Petitioner made to later treaters may suggest an onset of developmental-related symptoms earlier than six months, at best, even those statements put onset occurring three months after vaccination. Here, the temporal gap between receipt of the vaccines at issue and the documented beginning of A.N.'s developmental problems is demonstrably too great to suggest a causal relationship. *Thompson v. Sec'y of Health & Human Servs.*, No. 15-1498V, 2017 WL 2926614, at *14 (Fed. Cl. Spec. Mstr. May 16, 2017).

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caused autism. The OAP proceedings concluded in 2010.

II. Dismissal of the Claim is Appropriate at this Early Stage

A hearing provides a petitioner with the opportunity to put on live testimony, which aids the special master most in cases where witness credibility is at issue or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings. *See, e.g.*, *Hooker*, 2016 WL 3456435, at *21 (discussing a special master's discretion in holding a hearing and the factors that weighed against holding a hearing in the matter); *Murphy*, 1991 WL 71500, at *2 (no justification for a hearing where the claim is fully developed in the written records and the special master does not need to observe the fact witnesses for the purpose of assessing credibility). It may also permit a claimant to expand upon or illuminate points already set forth in paper filings, or respond to unanticipated questions raised in the matter – but again, only where necessary to reach a decision.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400-01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id.* Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing.

In this case, live witness testimony is not required in order for me to reach a reasoned decision. The flaws in Petitioner's theory and factual arguments are self-evident from review of the medical records.

At bottom, I cannot conclude that Petitioners' claim should proceed further, due to the lack of success of cases with factually similar circumstances and causation theories. The theory that the vaccines A.N. received could have caused her development of autism and other developmental problems, remains unreliable and lacks critical scientific support, especially given the weak facts of this case. Under such circumstances, allowing the matter to continue on does a disservice to Petitioner, while misallocating judicial resources away from cases in which factual and legal disputes warrant more attention.

CONCLUSION

The factual record does not support the Petitioner's contention that A.N. suffered from a as a result of receiving her MMR vaccine. Thus, Petitioner has not established entitlement to a damages award I must **DISMISS** their claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.[7]

IT IS SO ORDERED.

Brian H. Corcoran
Special Master

[7] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.